IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of			Dated: June 9, 2008
Keith K. Daellenbach			
Serial No.	:	10/085,564	Examiner Laura C. Schell
Filed	:	February 26, 2002	Group Art Unit 3767
For	:	END EFFECTOR FOR NEEDLE-FREE INJECTION SYSTEM	

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S i r :

BRIEF OF APPELLANT

This Brief is presented in opposition to the Examiner's final rejection of claims 1-25, 33, and 35-45 in the final Office action dated January 10, 2008.

I. REAL PARTY IN INTEREST

The real party in interest is Bioject Inc., the assignee of record, which is an Oregon corporation having a principal place of business at 20245 S.W. 95th Avenue, Tualatin, Oregon 97062, U.S.A. Bioject Inc. is a wholly-owned subsidiary of Bioject Medical Technologies, Inc., an Oregon corporation having a principal place of business at 20245 S.W. 95th Avenue, Tualatin, Oregon 97062, U.S.A..

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

The present application was filed on February 26, 2002, with original claims 1–32. In a response dated April 30, 2003, Appellant elected claims 1–25, with traverse, in response to a restriction requirement. In a response dated October 1, 2003, Appellant amended claims 1 and 19, cancelled claims 26–32 and added claim 33. In a response dated June 2, 2004, Appellant amended claims 1 and 19. In a response dated February 24, 2005, Appellant amended claims 1 and 19 and added claims 34–39. In a response dated August 19, 2005, Appellant amended claims 1 and 19 and added claims 40–43. In a response dated October 18, 2007, Appellant amended claims 1, 19, 24 and 25, cancelled claim 34, and added claims 44 and 45.

At the time of the Final Office action, mailed January 10, 2008 (hereinafter "Final Office action"), claims 1–25, 33 and 35-45 remained pending in the application. In the Final Office action, claims 1–25, 33 and 35-45 were rejected under 35 U.S.C. § 103(a).

Claims 1–25, 33 and 35-45, as amended in the response dated October 18, 2007, are the claims at issue in this appeal.

IV. STATUS OF AMENDMENTS

In a response dated March 6, 2008, Appellant amended claim 45. This response was denied entry, as indicated in an Advisory action dated March 28, 2008 (hereinafter "Advisory Action"). No other amendments have been made subsequent to the final Office action dated January 10, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The summary is set forth in illustrative embodiments, which are shown and described in the application as originally filed. Discussions of selected elements and

recitations of claimed subject matter can be found at least at the cited locations in the specifications and drawings. The claims of the present application are directed to needle-free jet injection devices and end effectors for needle-free injection devices.

In particular, independent claim 1 is directed to a needle-free jet injection device 10 for delivering a fluid into an internal organ, an example of which is shown in Figs. 1–8 and described in the specification on page 4, line 10, to page 12, line 21. The device 10 comprises a rigid end effector 14 (e.g., Figs. 1–8 and page 9, line 14 to page 12, line 21) having a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices 16, 116, 216, the end effector 14 including a rigid interior wall that defines a rigid fluid channel 18, where the end effector 14 is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel 18 has a cross section through which a central axis of the end effector 14 extends, and where the end effector 14 is configured to enable fluid to flow from the fluid channel 18 out through the plurality of orifices 16, 116, 216. The device 10 also comprises a fluid reservoir 17, 21 (e.g., Fig. 2 and page 6, line 12, to page 7, line 15) in fluid communication with the end effector 14. The device 10 also comprises an ejection mechanism (see e.g., Figs. 1 and 2 and page 4, line 10, to page 8, line 7) adapted to eject the fluid from the fluid reservoir 17, 21 through the end effector 14 and out of the orifices 16, 116, 216 with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ (see e.g., page 8, line 15, to page 9, line 5) and without penetration of the outer surface of the organ by the end effector 14, where the end effector 14 extends away from the ejection mechanism such that an operative end of the end effector 14 is spaced from the ejection mechanism.

Independent Claim 19 is directed to an end effector 14 (e.g., Figs. 1–8 and page 9, line 14 to page 12, line 21) for a needle-free injection device (e.g., device 10 as shown in Figs. 1–8 and described in the specification on page 4, line 10, to page 12, line 21) adapted to inject a fluid through an outer surface of an internal organ and into the internal organ, without penetration of the outer surface of the internal organ by the end effector and while maintaining functionality of the organ (see e.g., page 8, line 15, to page 9, line 5). The end effector 14 comprises a longitudinally rigid elongate shaft that extends away from the injection device to a blunt distal end and that includes a tubular fluid channel 18 fluidly and directly coupled with a plurality of orifices 16, 116, 216 through which the fluid may be ejected, wherein the elongate shaft is sufficiently rigid to maintain a longitudinal shape during use, where the tubular fluid channel 18 has a cross section through which a central axis of the end effector extends, and where the tubular fluid channel 18 includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices 16, 116, 216.

Independent Claim 45 is directed to a needle-free jet injection device 10 for delivering a fluid into selected internal tissue, an example of which is shown in Figs. 1–8 and described in the specification on page 4, line 10, to page 12, line 21. The device 10 comprises a body (e.g., 12 in Fig. 1) and a longitudinally rigid elongate member 14 (see e.g., Figs. 1–8 and page 9, line 14 to page 12, line 21) extending away from the body to a blunt distal end. The longitudinally rigid elongate member 14 comprises: a sidewall; a central longitudinal axis configured into a shape, wherein the longitudinally rigid elongate member 14 is sufficiently rigid to maintain the shape of its central longitudinal axis during use; at least one injection orifice 16, 116, 216 disposed on the sidewall,

wherein the at least one injection orifice 16, 116, 216 is oriented generally laterally to the central longitudinal axis; a fluid channel 18 extending substantially all the way from the body to the at least one injection orifice 16, 116, 216, wherein the fluid channel 18 has a cross section through which the central longitudinal axis extends; a straight shaft section; and a distal section 22, wherein at least a portion of a longitudinal axis of the distal section 22 is not collinear with a longitudinal axis of the straight shaft section (e.g., page 9, lines 15–18), at least one injection orifice 16, 116, 216 is disposed on the distal section 22, and the longitudinally rigid elongate member 14 is adapted to be positioned with the at least one injection orifice 16, 116, 216 adjacent the selected internal tissue. The device 10 also comprises a fluid reservoir 17, 21 (e.g., Fig. 2 and page 6, line 12, to page 7, line 15) in fluid communication with the fluid channel 18 and an ejection mechanism (see e.g., Figs. 1 and 2 and page 4, line 10, to page 8, line 7) disposed within the body, wherein the ejection mechanism is adapted to eject the fluid from the fluid reservoir 17, 21 through the fluid channel 18 and out of the at least one injection orifice 16, 116, 216 with sufficient pressure to penetrate the selected internal tissue while preserving functionality of the tissue (see e.g., page 8, line 15, to page 9, line 5) and without penetration of the selected internal tissue by the longitudinally rigid elongate member 14.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the Final Office action, claims 1–25, 33 and 35-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tom (U.S. Patent No. 7,211,063), either alone or variously in view of Glines et al. (US Patent No. 6,716,190), Paskar (US Patent No. 6,623,449), or Menne et al. (U.S. Patent No. 5,840,061). More specifically, claims

1–9, 14, 15, 19, 20, 22–25, 33 and 40–43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tom in view of Glines et al.. Claims 10–13 and 37–39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tom. Claims 16–18, 21, 35, 36 and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tom in view of Paskar. Claim 45 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Menne et al. in view of Tom.

The rejections of claims 1–25, 33 and 35-45 under 35 U.S.C. § 103(a) are at issue in this appeal.

VII. ARGUMENT

The Examiner has improperly rejected Appellant's claims under 35 U.S.C. § 103(a). When the claims are reviewed under the current standards for obviousness as set by the United States Supreme Court, the Federal Circuit Court of Appeals and the Board of Patent Appeals and Interferences, the impropriety of the rejections becomes clear.

A. Standards of Review

In ex parte patent prosecution, "the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

In order to support a finding that a claim is unpatentable as obvious under 35 U.S.C. § 103(a), an Examiner must provide an explicit analysis. In particular, "rejections

on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Thus, the Examiner must explicitly (1) determine the scope and content of the prior art; (2) ascertain the differences between the prior art and the claims at issue; (3) resolve the level of ordinary skill in the art; and (4) evaluate any objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). When ascertaining the differences between the prior art and the claims at issue, the Examiner must consider the invention defined in the claims as a whole. MPEP § 2141.02; *see also KSR*, 550 U.S. at ___, 82 USPQ2d at 1391 (quoting 35 U.S.C. § 103(a)). In particular, all claim elements must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, an Examiner cannot properly reject a claim as obvious under 35 U.S.C. § 103(a) and the applicant is entitled to a patent unless the Examiner explicitly articulates how the prior art discloses, teaches or suggests each and every element in the claim.

B. Rejections under 35 U.S.C. § 103(a) : Claims 1–25, 33, and 35–44

Claims 1–25, 33, and 35–44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tom, either alone or variously in view of Glines et al. or Paskar.

1. Claims 1, 2, 5, 10–18 and 35–43

In the Final Office action, the Examiner rejected claim 1 and primarily based on Tom. In particular, the Examiner asserted that Tom disclosed, taught, or would have suggested a needle-free jet injection device that includes many of the elements of the

needle-free jet injection device recited in claim 1. However, as will be discussed below, Tom does not disclose, teach, or even suggest many of the elements for which the Examiner cited Tom in the Final Office action.

As an initial matter, Appellant respectfully points out that the device shown in Fig. 1 of Tom (reproduced below) is not a needle-free jet injection device. Rather, Tom discloses a pressure sensor for a therapeutic delivery device. As shown in Fig. 1 and generally described at column 2, line 65 to column 3, line 34, Tom discloses an apparatus 44 for accessing a patient's tissue or organ region 47. The apparatus 44 includes a rigid shaft 46, which may have a curved section, a sensor device 20, and a handle 48. As shown in Fig. 2, the force contact transducer or sensor device 20 includes a cap 30 and a bio-compatible coating or cover 40. The force contact transducer or sensor device 20 is desirably sealed to "prevent ingress of bodily or other fluids into the electrical regions of the apparatus" (column 4, lines 53–55). The cover 40 also "prevent[s] fluid ingress" (column 5, lines 13–16).

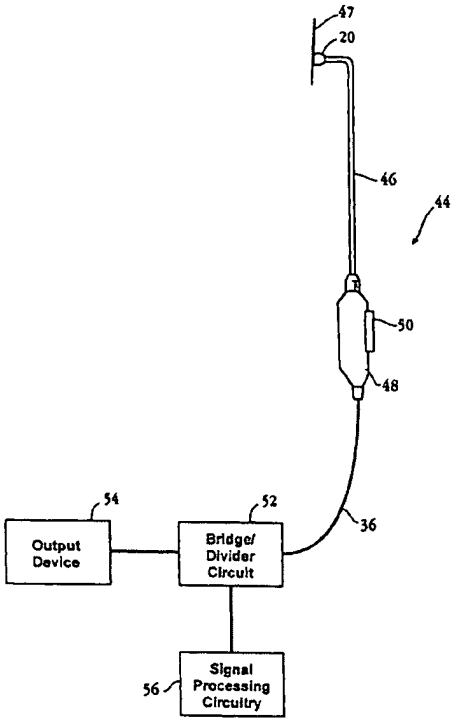


Fig. 1

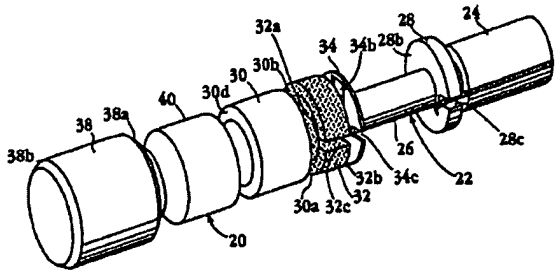


Fig. 2

As described at column 3, lines 35–48 of Tom, "handle 48 may be designed to produce a selected therapeutic effect on target tissue, when a desired pressure and/or pressure contact angle is sensed between the probe and target tissue." In particular and as cited by the Examiner in the Final Office action, the "therapeutic effect may be, for example, the injection, by a needle or needleless injection system" (column 3, lines 38–39). However, Tom does not disclose any structures or details of such a "needleless injection system." Rather, at column 3, lines 44–48, Tom merely makes a vague general reference that the "apparatus may therefore be equipped, according to well-known devices, to provide an extendable needle, a light fiber, an extendable mechanical-injury device, or the like to produce the desired therapeutic effect, in response to a signal applied by the user to handle 48." The mere naming of a

"needleless injection system" and a vague general reference to an apparatus "equipped, according to well-known devices" does not disclose, teach or suggest any structures or details regarding those devices.

Claim 1 recites a needle-free jet injection device for delivering a fluid into an internal organ. The needle-free jet injection device of claim 1 comprises:

> a rigid end effector having a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices, the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices;
>
> a fluid reservoir in fluid communication with the end effector; and
>
> an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the orifices with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ and without penetration of the outer surface of the organ by the end effector, where the end effector extends away from the ejection mechanism such that an operative end of the end effector is spaced from the ejection mechanism.

Contrary to the Examiner's assertions in the Final Office action, Tom does not disclose, teach, or even suggest many of the elements of the needle-free jet injection device of claim 1.

In particular, Tom does not disclose, teach, or even suggest a rigid end effector as recited in claim 1, which includes:

> a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices, the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices.

Tom does not disclose, teach, or even suggest many of these elements. For example, other than the aforementioned vague general reference to a "needleless injection system," Tom does not disclose, teach, or suggest even a single orifice. In addition, Tom does not disclose, teach, or even suggest a rigid interior wall that defines a rigid fluid channel. Further, because Tom does not disclose, teach, or even suggest a fluid channel, Tom cannot, and does not, disclose, teach, or even suggest that the fluid channel has a cross section through which a central axis of the end effector extends. Further, because Tom does not disclose, teach, or even suggest an orifice or a fluid channel, Tom cannot, and does not, disclose, teach, or even suggest that an end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices.

Furthermore, Appellant asserts that Tom teaches away from a modification or combination of the pressure sensor disclosed therein to include a plurality of orifices because, as noted above, the sensor is desirably sealed to "prevent ingress of bodily or other fluids into the electrical regions of the apparatus." The modification of the pressure sensor of Tom to include even a single orifice would disrupt any seal and would undesirably permit ingress of bodily or other fluids into the electrical regions of the apparatus, which could render the sensor inoperative or otherwise unsatisfactory for its intended purpose.

Tom does not disclose, teach, or even suggest a needle-free jet injection device that includes a fluid reservoir in fluid communication with the end effector. As noted above, Tom does not disclose, teach, or even suggest an end effector with which a fluid reservoir could be in communication. Furthermore, the ambiguous reference in Tom to

a "needleless injection system" that may be "equipped, according to well-known devices" does not disclose, teach, or even suggest a needle-free jet injection device that includes a fluid reservoir.

Tom does not disclose, teach, or even suggest an ejection mechanism, let alone an ejection mechanism as recited in claim 1, which is adapted to eject the fluid from the fluid reservoir through the end effector and out of the orifices with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ. As noted above, Tom does not disclose, teach, or even suggest a fluid reservoir from which, or orifices through which, fluid may be ejected. The ambiguous reference in Tom to a "needleless injection system" that may be "equipped, according to well-known devices" does not disclose, teach, or even suggest ejecting fluid with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ.

Furthermore, the discussion at column 2, lines 1–16 Tom regarding surface treatment and prevention of "perforation type injuries" is wholly irrelevant to ejecting fluid with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ. Rather, the cited discussion was part of the summary of the pressure sensor invention disclosed in Tom, not the "needleless injection system" that is vaguely referenced at column 3, lines 35–48. As described at column 2, lines 1–7, the pressure sensor invention of Tom "provide[s] information to the user of a medical instrument, such as a catheter, that must be placed in contact with the surface of an anatomical structure, to increase the likelihood of safely delivering the desired treatment while reducing the possibility of inflicting perforation type injuries or providing inadequate treatment." In particular, as described at column 2, lines 8–11, the

disclosure of Tom is directed toward "generating information regarding whether the tip of a medical instrument, such as a catheter or probe, is in contact with a surface of a tissue or organ, and, if so, the magnitude of the contact force." Information regarding (1) the existence of contact between the tip of a medical instrument and the surface of a tissue or organ or (2) the magnitude of any contact force has no relevance to a particular ejection pressure or pressure range that is sufficient to penetrate an outer surface of the organ while preserving functionality of the organ. Thus, Tom does not disclose, teach, or even suggest an ejection pressure, let alone a pressure sufficient to penetrate an outer surface of the organ while preserving functionality of the organ, as recited in claim 1.

In the Advisory Action, the Examiner stated that "the structure claimed is inherent in needle-less injectors and therefore would be obvious to have included it in the device of Tom." However, Appellant asserts that the Examiner has not offered any support for this proposition. Thus, Appellant respectfully requests that the Examiner has not established a *prima facie* case of obviousness because the Examiner has not explicitly articulated how the prior art discloses, teaches or suggests each and every element in claim 1.

For at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in claim 1. Claims 2, 5, 10–18 and 35–43 depend from claim 1. Claims 2, 5, 10–18 and 35–43, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 1. Accordingly, the rejections of claims 1, 2, 5, 10–18 and 35–43 under 35 U.S.C. § 103 are improper.

Thus, Appellant respectfully requests that the rejections of claims 1, 2, 5, 10–18 and 35–43 under 35 U.S.C. § 103 be withdrawn.

2. Claims 3 and 4

Claim 3, which depends from claim 1, recites that at least some of the orifices are located in the distal section. As noted above, Tom does not disclose, teach or suggest orifices, let alone the location of a particular orifice. Thus, for at least these additional reasons, Tom does not disclose, teach or suggest a device as claimed in claim 3. Claim 4 depends from claim 3 and is thus allowable for at least the reasons stated above with respect to claim 3. Accordingly, the rejections of claims 3 and 4 under 35 U.S.C. § 103 are improper. Thus, Appellant respectfully requests that the rejections of claims 3 and 4 under 35 U.S.C. § 103 be withdrawn.

3. Claims 6 and 7–9

Claim 6, which depends from claim 1, recites that "the pressure with which the fluid is ejected through the orifice is sufficient to cause a transmural lesion in the organ." As described at lines 2–4 on page 9 of the specification of the present application, transmural refers to fluid penetration throughout the entire wall thickness of an organ. Furthermore, the Free Online Medical Dictionary, Thesaurus and Encyclopedia defines transmural as "extending through or affecting the entire thickness of a wall of an organ or cavity" (http://medical-dictionary.thefreedictionary.com/transmural). In contrast, the portions of Tom cited by the Examiner (i.e., the abstract, column 1, lines 16–61, and column 2, lines 1–7) at most disclose that the pressure sensor invention of Tom may be used to provide contact information while treating the wall of the heart, with the contact information being usable to avoid perforation of the organ wall. However, such

disclosure is wholly irrelevant to whether a needle-free jet injection device causes a transmural lesion in an organ. Thus, Tom does not disclose, teach, or even suggest causing a transmural lesion in an organ.

Furthermore, as noted above, Tom does not disclose, teach, or even suggest an ejection pressure. Thus, Tom cannot, and does not, disclose, teach, or even suggest an ejection pressure sufficient to cause a transmural lesion in an organ.

For at least these additional reasons, Tom does not disclose, teach or suggest a device as claimed in claim 6. Claims 7–9 depend from claim 6 and are thus allowable for at least the reasons stated above with respect to claim 6. Accordingly, the rejections of claims 6–9 under 35 U.S.C. § 103 are improper. Thus, Appellant respectfully requests that the rejections of claims 6–9 under 35 U.S.C. § 103 be withdrawn.

4. Claim 33

Claim 33, which depends from claim 1, recites that the fluid channel is cylindrical. As noted above, Tom does not disclose, teach, or even suggest a fluid channel. Thus, Tom cannot, and does not, disclose, teach, or even suggest that the fluid channel is cylindrical. For at least this additional reason, Tom does not disclose, teach or suggest a device as claimed in claim 33. Accordingly, the rejection of claim 33 under 35 U.S.C. § 103 is improper. Thus, Appellant respectfully requests that the rejection of claim 33 under 35 U.S.C. § 103 be withdrawn.

5. Claims 19–25 and 44

Claim 19 recites an end effector for a needle-free injection device adapted to inject a fluid through an outer surface of an internal organ and into the internal organ,

without penetration of the outer surface of the internal organ by the end effector and while maintaining functionality of the organ. The end effector of claim 19 comprises:

> a longitudinally rigid elongate shaft that extends away from the injection device to a blunt distal end and that includes a tubular fluid channel fluidly and directly coupled with a plurality of orifices through which the fluid may be ejected, wherein the elongate shaft is sufficiently rigid to maintain a longitudinal shape during use, where the tubular fluid channel has a cross section through which a central axis of the end effector extends, and where the tubular fluid channel includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices.

Contrary to the Examiner's assertions in the Final Office action, Tom does not disclose, teach, or even suggest many of these elements. For example, as noted above, Tom does not disclose, teach, or even suggest any orifices. Rather, as noted above, Tom teaches away from a modification or combination that includes any orifices. In addition, because Tom does not disclose, teach, or even suggest any orifices, Tom cannot, and does not, disclose, teach, or even suggest a tubular fluid channel, let alone a tubular fluid channel that is fluidly and directly coupled with a plurality of orifices through which the fluid may be ejected. Further, because Tom does not disclose, teach, or even suggest a tubular fluid channel or any orifices, Tom cannot, and does not, disclose, teach, or even suggest that the tubular fluid channel has a cross section through which a central axis of an end effector extends or that the tubular fluid channel includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices.

Thus, for at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest an end effector as claimed in amended claim 19. Claims 20–25 and 44 depend from claim 19. Claims 20–25 and 44, each of which contains further limitations that distinguish the cited references, are thus

allowable for at least the reasons stated above with respect to claim 19. Accordingly, the rejections of claims 19–25 and 44 under 35 U.S.C. § 103 are improper. Thus, Appellant respectfully requests that the rejections of claims 19–25 and 44 under 35 U.S.C. § 103 be withdrawn.

C. Rejection under 35 U.S.C. § 103 : Claim 45

Claim 45 was rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. in view of Tom.

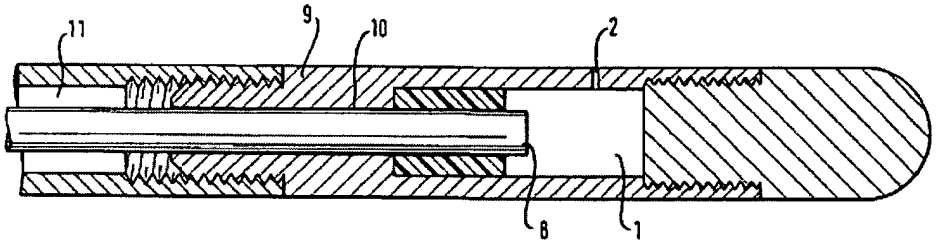
Claim 45 recites a needle-free jet injection device for delivering a fluid into selected internal tissue. The needle-free jet injection device of claim 45 comprises:

> a body;
> a longitudinally rigid elongate member extending away from the body to a blunt distal end, the longitudinally rigid elongate member comprising:
> a sidewall,
> a central longitudinal axis configured into a shape, wherein the longitudinally rigid elongate member is sufficiently rigid to maintain the shape of its central longitudinal axis during use,
> at least one injection orifice disposed on the sidewall, wherein the at least one injection orifice is oriented generally laterally to the central longitudinal axis,
> a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the fluid channel has a cross section through which the central longitudinal axis extends,
> a straight shaft section, and
> a distal section, wherein at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section, at least one injection orifice is disposed on the distal section, and the longitudinally rigid elongate member is adapted to be positioned with the at least one injection orifice adjacent the selected internal tissue;
> a fluid reservoir in fluid communication with the fluid channel; and
> an ejection mechanism disposed within the body, wherein the ejection mechanism is adapted to eject the fluid from the fluid reservoir through the fluid channel and out of the at least one injection orifice with sufficient pressure to penetrate the selected internal tissue while

preserving functionality of the tissue and without penetration of the selected internal tissue by the longitudinally rigid elongate member.

Contrary to the Examiner's assertions in the Final Office action, Menne et al. does not disclose a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the fluid channel has a cross section through which the central longitudinal axis extends. Rather, Appellant respectfully points out that Menne et al. discloses an annular fluid channel through which the longitudinal axis does not pass. As shown in Fig. 2 of Menne et al. (reproduced below), the distal end of a driving piston or probe 8 delimits a pressure chamber 1 that contains liquid flowing into an ejection opening 2 (column 4, lines 56–62). A "narrow liquid flow-through slit 10" remains between the probe 8 and the guiding member 9 where the probe 8 passes through the guiding member 9, with the liquid flow-through slit 10 running "into a liquid supply channel 11 surrounding the probe 8" (column 5, lines 3–8). The probe 8 is solid, such that the liquid flow-through slit 10 and liquid supply channel 11 are thus annular fluid channels. As shown in Fig. 2 of Menne et al., the annular liquid flow-through slit 10 and liquid supply channel 11 are both approximately centered relative to the guiding member 9 such that a central longitudinal axis of the guiding member 9 would not be within the fluid in the fluid channel (i.e., the liquid flow-through slit 10 and the liquid supply channel 11), as recited in claim 45. Rather, the central longitudinal axis of the guiding member 9 would be within the solid probe 8, not within the fluid channel.

Fig. 2



Furthermore, as discussed above Tom does not disclose any structures or details of any "needleless injection system." Thus, Contrary to the Examiner's assertions in the Final Office action, Tom cannot, and does not, disclose, teach, or even suggest a needle-free jet injection device as recited in claim 45, in which a longitudinal axis of a distal section is not collinear with a longitudinal axis of a straight shaft section.

Thus, for at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a needle-free jet injection device as claimed in claim 45. Thus, claim 45 patentably distinguishes the cited art. Accordingly, the rejection of claim 45 under 35 U.S.C. § 103 is improper. Thus, Appellant respectfully requests that the rejection of claim 45 under 35 U.S.C. § 103 be withdrawn.

VIII. CLAIMS APPENDIX

1. (Previously presented) A needle-free jet injection device for delivering a fluid into an internal organ, the device comprising:

a rigid end effector having a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices, the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices;

a fluid reservoir in fluid communication with the end effector; and

an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the orifices with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ and without penetration of the outer surface of the organ by the end effector, where the end effector extends away from the ejection mechanism such that an operative end of the end effector is spaced from the ejection mechanism.

2. (Original) The device of claim 1, wherein the end effector includes a straight shaft section and a distal section.

3. (Original) The device of claim 2, wherein at least some of the orifices are located in the distal section.

4. (Original) The device of claim 3, wherein all of the orifices are located in the distal section.

5. (Original) The device of claim 1, wherein the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the fluid reservoir.

6. (Original) The device of claim 1, wherein the pressure with which the fluid is ejected through the orifice is sufficient to cause a transmural lesion in the organ.

7. (Original) The device of claim 6, wherein the organ is a heart.

8. (Original) The device of claim 7, wherein the fluid includes ethanol.

9. (Original) The device of claim 6, wherein the transmural lesion is sufficient to prevent electrical signals from traveling through the transmural lesion.

10. (Original) The device of claim 1, wherein length of the end effector is between four and ten inches.

11. (Original) The device of claim 1, wherein the outer diameter of the end effector is between 0.100 and 0.300 inches.

12. (Original) The device of claim 1, wherein the inner diameter of the end effector is between 0.050 and 0.275 inches.

13. (Original) The device of claim 2, wherein the length of the distal section is between 0.50 and 2.00 inches.

14. (Original) The device of claim 2, wherein the distal section lies at an angle between 30 and 90 degrees relative to the shaft.

15. (Original) The device of claim 2, wherein the distal section lies at a 45 degrees angle relative to the shaft.

16. (Original) The device of claim 1, wherein at least some of the orifices are arranged linearly along the length of the end effector.

17. (Original) The device of claim 1 wherein the orifices are arranged in multiple rows along the length of the end effector.

18. (Original) The device of claim 1 wherein the rows are offset from each other.

19. (Previously presented) An end effector for a needle-free injection device adapted to inject a fluid through an outer surface of an internal organ and into the internal organ, without penetration of the outer surface of the internal organ by the end effector and while maintaining functionality of the organ, the end effector comprising a longitudinally rigid elongate shaft that extends away from the injection device to a blunt distal end and that includes a tubular fluid channel fluidly and directly coupled with a plurality of orifices through which the fluid may be ejected, wherein the elongate shaft is sufficiently rigid to maintain a longitudinal shape during use, where the tubular fluid channel has a cross section through which a central axis of the end effector extends, and where the tubular fluid channel includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices.

20. (Original) The device of claim 19, wherein the end effector includes a straight section and a distal section.

21. (Original) The device of claim 19, wherein the orifices are arranged linearly along the length of the end effector.

22. (Original) The device of claim 21, wherein at least some of the orifices are located in the distal section.

23. (Original) The device of claim 22, wherein all of the orifices are located in the distal section.

24. (Previously presented) The device of claim 20, wherein the distal section is angled relative to the straight section.

25. (Previously presented) The device of claim 20, wherein the distal section is curved.

26–32. (Cancelled).

33. (Previously presented) The device of claim 1, wherein the fluid channel is cylindrical.

34. (Cancelled)

35. (Previously Presented) The device of claim 1, wherein at least some of the orifices are oriented in a direction generally lateral to the central axis of the end effector.

36. (Previously Presented) The device of claim 35, wherein all of the orifices are oriented in a direction generally lateral to the central axis of the end effector.

37. (Previously Presented) The device of claim 6, wherein the pressure with which the fluid is ejected through the orifice is less than about 4000 psig.

38. (Previously Presented) The device of claim 37, wherein the pressure with which the fluid is ejected through the orifice is less than about 2100 psig.

39. (Previously Presented) The device of claim 38, wherein the pressure with which the fluid is ejected through the orifice is less than about 1100 psig.

40. (Previously Presented) The device of claim 2, wherein a longitudinal axis of the distal section is collinear with a longitudinal axis of the straight shaft section.

41. (Previously Presented) The device of claim 2, wherein at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section.

42. (Previously Presented) The device of claim 41, wherein at least a portion of the longitudinal axis of the distal section lies at an angle between 30 and 90 degrees relative to at least a portion of the longitudinal axis of the straight shaft section.

43. (Previously Presented) The device of claim 41, wherein at least a portion of the longitudinal axis of the distal section lies at an angle of approximately 45 degrees relative to the longitudinal axis of the straight shaft section.

44. (Previously Presented) The device of claim 21, wherein at least some of the orifices are oriented in a direction generally lateral to the central axis of the end effector.

45. (Previously Presented) A needle-free jet injection device for delivering a fluid into selected internal tissue, the device comprising:

a body;

a longitudinally rigid elongate member extending away from the body to a blunt distal end, the longitudinally rigid elongate member comprising:

a sidewall,

a central longitudinal axis configured into a shape, wherein the longitudinally rigid elongate member is sufficiently rigid to maintain the shape of its central longitudinal axis during use,

at least one injection orifice disposed on the sidewall, wherein the at least one injection orifice is oriented generally laterally to the central longitudinal axis,

a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the fluid channel has a cross section through which the central longitudinal axis extends,

a straight shaft section, and

a distal section, wherein at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section, at least one injection orifice is disposed on the distal section, and the longitudinally rigid elongate member is adapted to be positioned with the at least one injection orifice adjacent the selected internal tissue;

a fluid reservoir in fluid communication with the fluid channel; and

an ejection mechanism disposed within the body, wherein the ejection mechanism is adapted to eject the fluid from the fluid reservoir through the fluid channel and out of the at least one injection orifice with sufficient pressure to penetrate the selected internal tissue while preserving functionality of the tissue and without penetration of the selected internal tissue by the longitudinally rigid elongate member.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

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I hereby certify that this correspondence is being filed electronically via the EFS-Web system at www.uspto.gov on June 9, 2008.

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